

Current Good Manufacturing Practices for Food

Title 21 Code of Federal Regulations (CFR)
Part 117, Subpart B



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Part 117 – What applies to me?



Part 117 – What applies to me?

- Sales <\$1,000,000
 - Subpart A – General Provisions
 - **Subpart B – Current Good Manufacturing Practice**
 - Subpart D – Modified Requirements
 - Subpart F – Records
- Sales ≥\$1,000,000
 - All of the above (except D)
 - Subpart C – Hazard Analysis & Risk-Based Preventive Controls
 - Subpart G – Supply-Chain Program

Presentation Goals

Key Terms

Four Major Components

Questions

Key Terms

Must* – mandatory.
Replaced “shall,”
which was defined

Adequate – what is *needed to accomplish the intended purpose in keeping with good public health practice*

Should – and all advisory language removed

Suitable* – adapted to a use or purpose; proper; able; qualified

* Dictionary Definitions

Preventing Contamination

Food



Food Contact Surfaces

Food Packaging Materials







Grounds

The grounds under control of the operator must be maintained in a manner to protect against the contamination of food.

21 CFR §117.20(a)(1-4)

Storing equipment

Litter and waste

Weeds and grass

Roads and yards

Drainage

Waste systems

Grounds

The grounds not under control of the operator and not adequately maintained: care shall be exercised to prevent food contamination through:

§117.20(a)(5)

Inspection

Extermination

Other means



Facilities

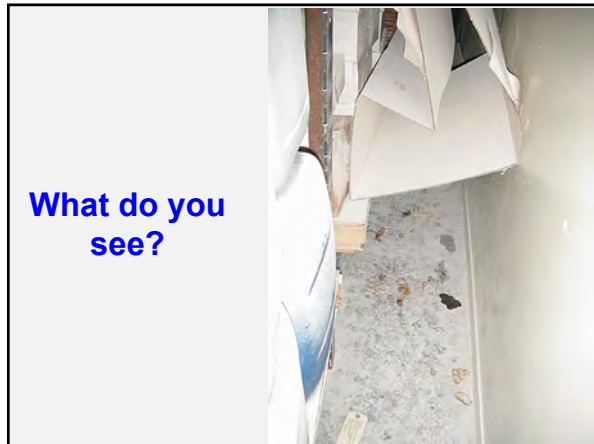
Buildings and structures **must** be of suitable size, construction, and design to facilitate maintenance and sanitary operations

§117.20(b)(1), (2)

- Space for equipment and storage
- Food safety + allergen controls
- Operating practices
- Effective design
- Other effective means











Your facility design must allow for product protection via either:

- Partition
- Space
- Time



Facilities

Plant buildings and structures **must** be suitable in size, construction and design to facilitate maintenance and sanitary operations. **§117.20(b)(5)**

- Adequate lighting
- Safety fixtures



Facilities

Buildings and structures **must** be of suitable size, construction, and design to facilitate maintenance and sanitary operations

§117.20(b)(3)

Outdoor Bulk Vessels

Construction

- adequately cleaned
- adequate space
- good repair

§117.35(a)

Facilities

Buildings and structures must be of suitable size construction and design to facilitate maintenance and sanitary operations

§117.20(b)(4)

Construction

- drip and condensate





Facilities

Buildings and structures **must** be suitable in size, construction and design to facilitate maintenance and sanitary operations.

§117.20(b)(6)

- Adequate ventilation

Sanitary Facilities §117.37(b), (c), (f)

Each plant **must** be equipped with **adequate sanitary facilities**

- Plumbing
 - Properly sized
 - Avoid being a source of contamination
 - Floor drainage
 - No back flow or cross connections
- Sewage disposal
- Rubbish and offal disposal





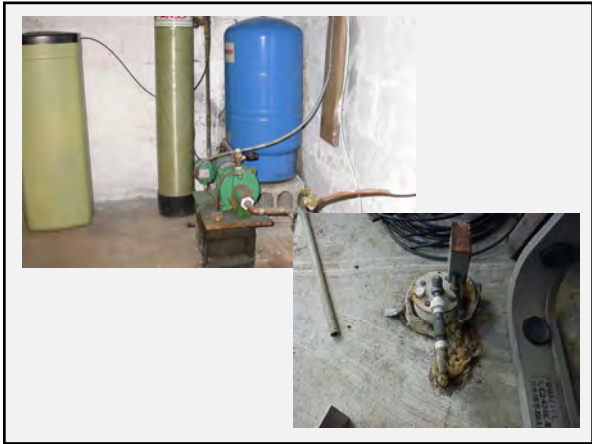
Water Supply

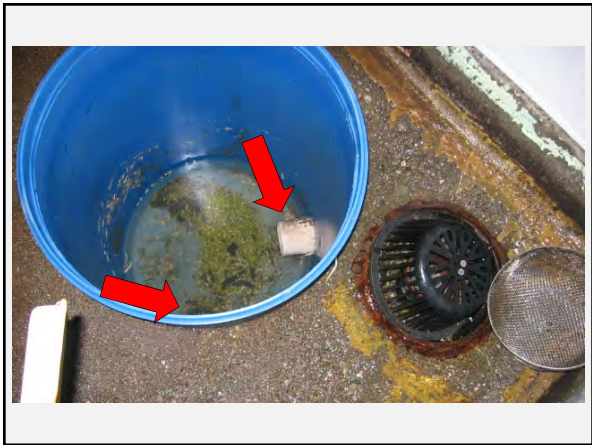
§117.37(a)

- Adequate Source
- Safe and Sanitary Quality
- Suitable Temperature
- Appropriate Pressure

§117.80(b)(1)

- Water used for washing, rinsing, or conveying food must be of safe and sanitary quality
- Water, if reused cannot increase the level of contamination in food







Sanitary Facilities §117.37(d)

Toilet Facilities

- Adequate, readily accessible
- Must be kept clean
- Must not be a **potential** source of contamination



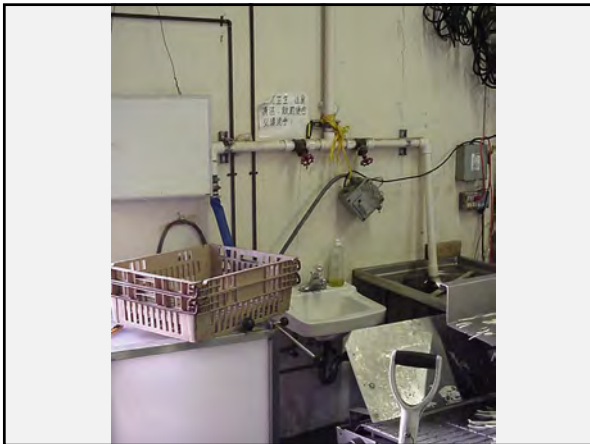




Sanitary Facilities §117.37(e)

Handwashing Facilities

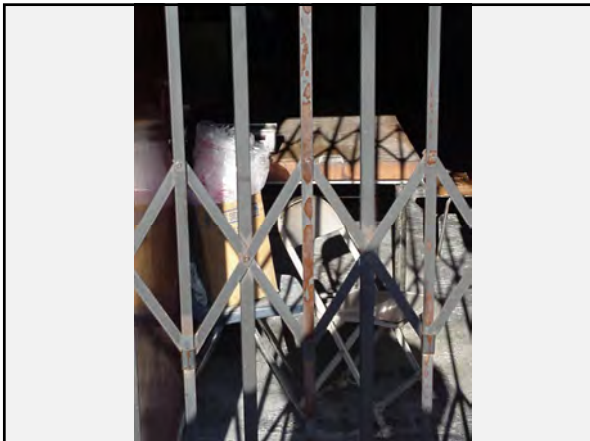
- To ensure hands are not a source of contamination
- Adequate (soap, towels)
- Convenient
- Running water at suitable temperature





Pest Control §117.20(b)(7)

Provide adequate screening or other protection against pests.





Pest Control §117.35(c)

- No pests allowed in plant
- Take effective measures to exclude from processing areas
- Pesticide use permitted only under precautions + restrictions







Personnel §117.10(a)

Management must take reasonable measures to ensure:

Disease control

- Medical Exam
- Observation
- Exclusion
- Reporting

Personnel

§117.10(b)

Management must take reasonable measures to ensure:

Cleanliness through hygienic practices

- Outer garments
- Personal cleanliness
- Washing hands thoroughly



Personnel

§117.10(b)

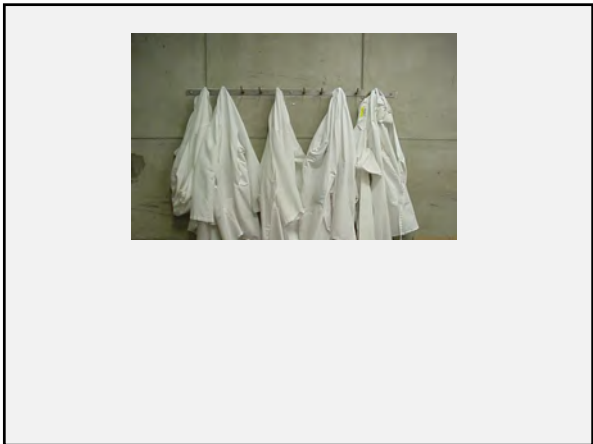
Management must take reasonable measures to ensure:

Cleanliness through hygienic practices

- Jewelry
- Gloves
- Hair restraints
- Clothing storage areas
- Confine eating, drinking, smoking
- Allergen cross-contact
- Foreign substances









Personnel

Management must take reasonable measures to ensure:

Education and Training
§117.4(b) and (d), and 117.9

Proper Supervision
§117.4(b) and (c)





Equipment

Must be designed and of such material, and workmanship to be **adequately cleanable and maintained** §117.40

- Avoid adulteration with:
 - lubricants
 - fuel
 - metal fragments
 - contaminated water
- Facilitate cleaning and maintenance



Equipment

§117.40(a), (b)

- Designed to withstand food, cleaning and sanitizing
- Smoothly bonded seams
- Taken apart for thorough cleaning

§117.80(c)(1)



Equipment

§117.40(a)

Must be:

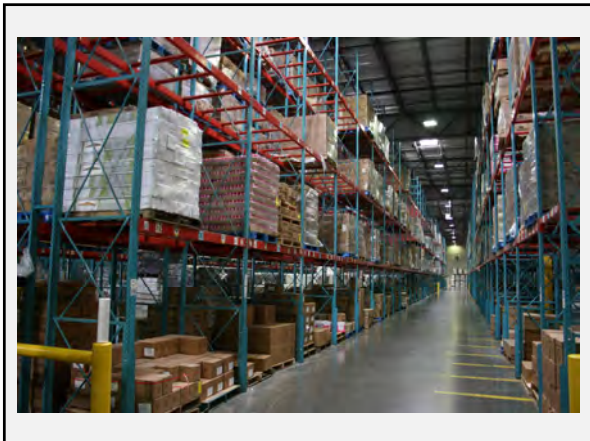
- Installed and maintained to facilitate cleaning
- Corrosion resistant
- Non-toxic

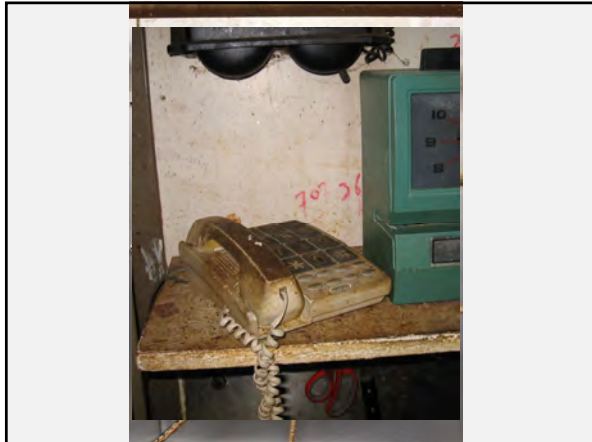


Equipment

Non-food contact surfaces

- **Constructed to be kept clean**
§117.40(c)
- **Cleaned as necessary to protect against allergen cross-contact and contamination**
§117.35(e)

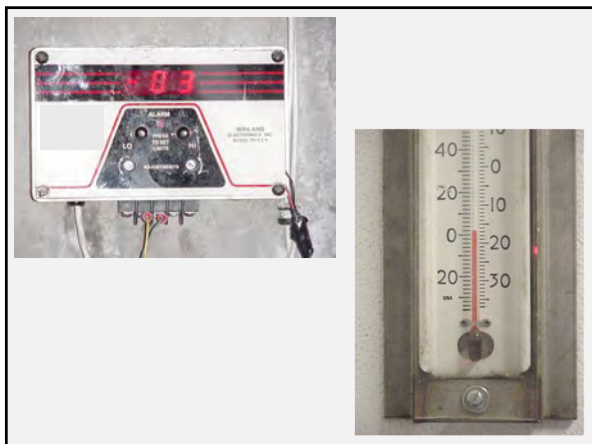




Equipment

§117.40(e)

Accurate temperature measuring or recording devices required for freezers and cold storage units



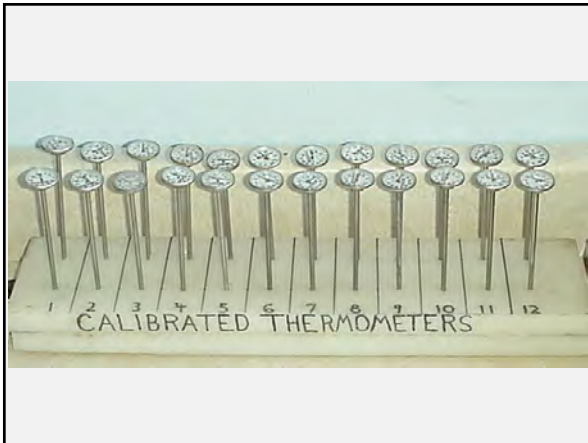
Equipment

§117.40(f) and (g)

Instruments and controls for measuring conditions that prevent the growth of microorganisms must be:

- accurate and precise
- maintained
- adequate in number

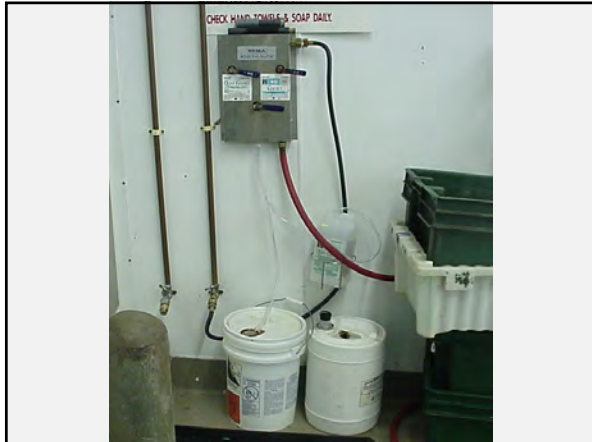
Compressed air must not be a source of contamination

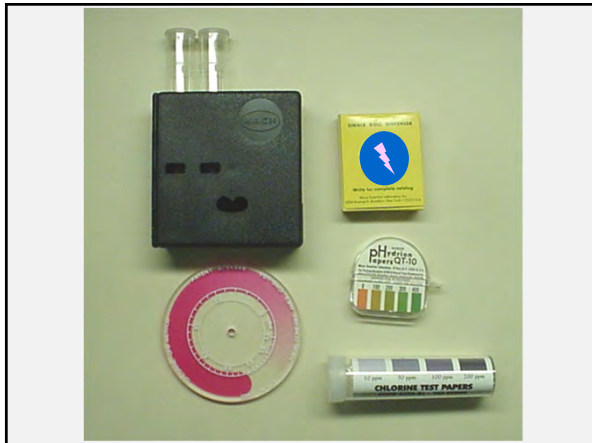


Sanitary Operations

§117.35(a)

Cleaning and sanitizing of **utensils** and **equipment** must be conducted in a manner that protects against allergen cross-contact and contamination





Sanitary Operations §117.35(b)(1)

Cleaning and sanitizing agents must be:

- Free from microorganisms
- Safe
- Adequate

Must be Verified by either:

- Letter of Guarantee,
- Certification, or,
- Examination

Sanitary Operations §117.35(b)

Use or store toxic agents only for:

- Cleaning and sanitizing
- Laboratory
- Maintenance and operations



Sanitary Controls §117.35(b)(2)

Toxic Agents must be:

- Identified: Labels!
- Held and stored to protect against contamination





Sanitation of Food Contact Surfaces
§117.35(d)

Must be cleaned as frequently as necessary to protect from allergen cross-contact and contamination.

- **Wet Sanitation**
- **Dry Sanitation**

Sanitation of Food Contact Surfaces

§117.35

Single service articles §117.35(d)

Sanitizing agents §117.35(e)

Portable equipment §117.35(f)



Processes and Controls

§117.80

All operations must be conducted in accordance with adequate sanitation principles

Appropriate quality control operations must be employed

Adequate precautions must be taken to protect from allergen cross-contact and contamination

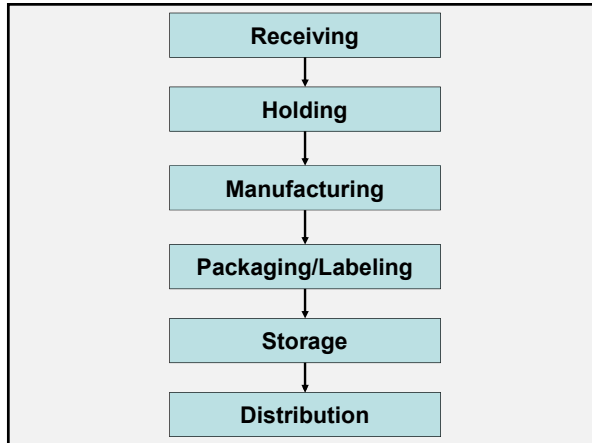
Processes and Controls

§117.80(b)(2)

Ingredients **must** not contain levels of microorganisms that may be injurious to health,

or

Ingredients **must** be pasteurized or otherwise treated.



Raw Materials

Manufacturing Operations

Raw Materials

§117.80(b)(1)

Must be:

Inspected, segregated or handled as necessary, to determine they are clean and suitable

Stored while protecting from allergen cross-contact and contamination, and minimizing deterioration

Washed and cleaned as necessary, to remove contaminants

Acceptable food storage practice?



Raw Materials

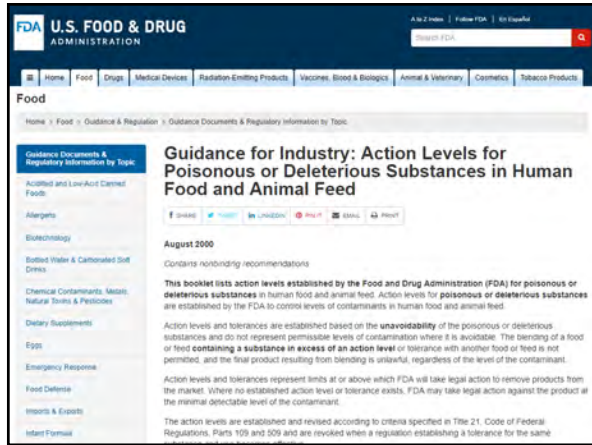
§117.80(b)(1)

Raw Materials and Ingredients must be inspected to ensure they are clean and suitable, and stored in a way to prevent allergen cross-contact, contamination, and deterioration.

Raw Materials

§117.80(b)(3)

Susceptible to **afatoxin** or other **natural toxins** must comply with FDA regulations, guidelines, and action levels.



| | |
|---|--|
| Action Levels for Poisonous or Deleterious Substances | Aflatoxin |
| | Aldrin & Dieldrin |
| | Benzene Hexachloride |
| | Cadmium |
| | Chlordane |
| | Chlordecone (Kepone) |
| | Dicofol (Kelthane) |
| | DDT, DDE, TDE |
| | Dimethylnitrosamine (Nitrosodimethylamine) |
| | Ethylene Dibromide (EDB) |
| | Heptachlor & Heptachlor Epoxide |
| | Lead |
| | Lindane |
| | Mercury |
| | Methyl Alcohol |
| | Mirex |
| | N-Nitrosamines |
| Paralytic Shellfish Toxin | |
| Polychlorinated Biphenyls (PCBs) | |

Raw Materials

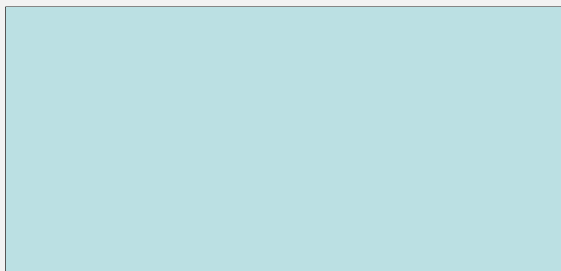
§117.80(b)(4), §117.110

Susceptible to **pests** or other **undesirable microorganisms or extraneous materials** shall comply with FDA defect action levels.



Defect Action Levels Handbook

Cocoa Beans



Raw Materials

§117.80(b)(5), (b)(7)

- Held in **bulk containers** must be held while protecting from allergen cross-contact, contamination, and adulteration
- Materials scheduled for **re-work** must be identified as such

Raw Materials

§117.80(b)(6)

Frozen ingredients must be kept frozen. If thawed, it must be done in a manner that prevents adulteration.

Manufacturing Operations

§117.80(c)

Comply by **monitoring**:

Physical Factors

- Time
- Flow Rate
- Aw
- pH
- Temperature
- Pressure
- Humidity

Manufacturing

- Freezing
- Dehydration
- Heat Processing
- Acidification
- Refrigeration
- Irradiation

Manufacturing Operations

§117.80(c)

All food manufacturing, including packaging and storage, must be conducted under conditions and controls necessary to minimize the potential for growth of microorganisms, allergen cross-contact, contamination, and deterioration.





Manufacturing Operations

§117.80(c)(3)

FOODS THAT CAN SUPPORT THE RAPID GROWTH OF UNDESIRABLE MICROORGANISMS MUST BE HELD AND PROCESSED IN A MANNER THAT PREVENTS THE FOOD FROM BECOMING ADULTERATED

Manufacturing Operations

H&SC §110980, 21 CFR §117.80(c)(3)

- Refrigerated foods at $\leq 45^{\circ}\text{F}$
- Frozen foods in frozen state
- Heat treating or acidifying foods held at ambient temperatures in hermetically sealed containers





Exercise

Additional Considerations

- **Hazard Analysis and Risk Based Preventive Controls**
 - Food Allergen/Sanitation/Supply-Chain Controls
 - Recall Plan
 - Environmental Monitoring Program
- Reportable Food Registry
- FDA Bioterrorism Registration
- Validation of Processes
- Audit Programs (ISO/SQF/ETC)

Contacts

State Government

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